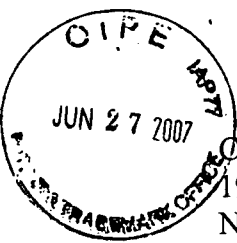


Ifw



CLC Nutraceuticals, LLC
191 Spring Road
North Kingston, Rhode Island 02852
(401)8867600

June 22, 2007

VIA FACSIMILE 1-571-273-8300

Ms. Patricia Leith, Examiner
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Re: Patent Application 10/800,608

Dear Ms. Leith:

Pursuant to our telephone conversation last week with you, please find enclosed herewith an Affidavit of Stephen T. Carney outlining the facts regarding the publication of our study. Also, please provide us with any additional requirements you are requesting from him to prove that the Study is NOT prior art. Finally, as we discussed, you have dropped your rejection based on the Muldoon article as prior art.

Please contact Mr. Carney at your earliest convenience with any questions or additional items you may require so we can proceed with obtaining patent protection for NCB.

Thank you for your anticipated cooperation in this matter.

Respectfully

A handwritten signature in black ink, appearing to read "Jack J. Vultaggio, Jr.", written over a circular stamp.

Jack J. Vultaggio, Jr.
Secretary General

Enclosures 12 pages



**United States Patent & Trademark Office
Rule 132 Affidavit**

Appl. No. : 10/800,608
Applicant : Stephen Truesdale Carney
Filed : March 15, 2004
TC/A.U. : 1655
Examiner : Patricia A. Leith

Affidavit of Stephen Truesdale Carney

I, Stephen Truesdale Carney, hereby duly depose and say as follows:

1. I hired Lawrence D. Rink, M.D. FACC ("Dr. Rink"), to conduct the Folic Acid and Alfalfa, The FALL Study, (the "Study") described and made part of the above referenced Patent Application. For your convenience, a copy of said Study is included herewith as Exhibit A. The purpose of the Study was to prove the claims made in the above referenced Patent Application filed on March 15, 2004.
2. On my behalf, Dr. Rink completed the Study on February 12, 2002 at which time he signed and dated the Study.
3. Dr. Rink has never published the Study. See Second Affidavit of Lawrence D Rink, M.D. FACC included herewith for your convenience as Exhibit B.
4. On June 7, 2003, during the construction of my company's website, NCB3.COM, I published the Study on NCB3.COM. See Archive of Website included herewith as Exhibit C.
5. Our first website was completed and was fully operational for the public on November 18, 2003. See Exhibit C.
6. On July 19, 2003, I spoke at a conference presented by the International Sprout Growers Association at which I provided to the attendees our findings from the Study. The Study was later published on the website of one of the conference participants International Specialty Supply. This is the publication you referenced in your last rejection letter to me.
7. To the best of my knowledge, the Study was not published before June 7, 2003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Signed under the pains and penalties of perjury this 21st day of June, 2007.



Stephen T. Carney

EXHIBIT A

[0043] *The Study.*

FOLIC ACID AND ALFALFA The FALL Study

Background:

There have been reports that alfalfa sprouts will lower total cholesterol and LDL levels in the blood. This has not been tested in a prospective, randomized or blinded trial.

Methods and Results:

45 patients, most with known coronary artery disease and many under treatment for hyperlipidemia were selected for the study. Patients were randomly assigned to either Group A placebo, Group B low dose alfalfa, and 230 mcg of folic acid, or Group C double dose alfalfa and folic acid.

The trial was 6 weeks and all patients were instructed to follow a low fat, low cholesterol diet, perform regular exercise in moderation, and to take the medication regularly. Group A (placebo)-one capsule per day, group B-two capsules per day, and group C-two capsules twice per day.

	Group A	Group B	Group C
LDL	5.9% decrease	16.6% decrease	8.6% decrease
HDL	3.2% decrease	11.2% increase	1.5% increase
C-reactive protein	33.6% increase	24.4% decrease	50.4% decrease
Homocysteine	5.6% increase	11.5% decrease	6.3% decrease
Triglycerides	2.4% decrease	1.4% decrease	15.0% decrease

Statement:

Cardiovascular disease is the most common cause of death and disability in the United States. More people die from cardiovascular disease than all of the other causes of death combined. Cardiovascular disease has been the most common cause of death in the United States since 1900 with the exception of the year 1918, during a flu outbreak. Multiple epidemiologic and clinical blinded prospective studies have indicated that lowering LDL levels will decrease the risk of cardiac events in primary prevention and will decrease recurrent cardiac events and decrease mortality in secondary prevention. The FDA has approved many drugs to be used in lipid lowering. Approximately 15 billions dollars per year is spent on lipid lowering medications. An equal amount of money is estimated to be spent on dietary and herbal supplements that do not require FDA approval and which are primarily directed toward lowering the risk of cardiovascular events. There are reports that alfalfa sprouts will lower serum cholesterol LDL levels and possibly raise HDL levels.

Prospective studies using diet as a means of controlling risk factors for cardiac events and decreasing cardiac events have been disappointing. The information regarding omega-3 fatty acids probably offers our best opportunity in this regard. The Adult Treatment Panel III has recommended lifestyle changes including exercise and dietary modification as a major means of lowering cardiovascular risk and future cardiac events.

Among a list of emerging “risk factors” are homocysteine levels and C-reactive protein. Elevated levels of homocysteine are positively correlated with risk for CHD. Folic acid and possibly B vitamins 6 and 12 have been documented to lower homocysteine levels.

C-reactive protein (CRP) is a marker for inflammation. Coronary artery disease is an inflammatory disease and there is now substantial evidence that persons with elevated high sensitivity C-reactive protein (hs-CRP) are at increased risk for future cardiac events. Inflammation within coronary plaques leads to plaque rupture and cardiac events. Statin drugs and a healthy lifestyle are known to reduce high sensitivity C-reactive protein. The Writing group of the 2002 workshop on inflammation markers and cardiovascular disease recommended measurement of hs-CRP in conjunction with other risk factors in people with increased risk of coronary artery disease. In many studies hs-CRP has been a better predictor of future cardiac events than LDL.

With this in mind, we undertook a study to determine the effects of alfalfa sprouts and folic acid on known risk factors of coronary artery disease including total cholesterol, LDL, HDL, triglycerides, high sensitivity C-reactive protein, homocysteine levels, and apolipoprotein (b).

All patients were already under some form of treatment for hyperlipidemia. The patients were advised not to change their medication prior to enrollment to the study or during the trial. The study was first discussed with the patients and they were supplied capsules which either contained placebo, Group B 560 mg of alfalfa sprout powder and 230 mcg of folic acid, 2 capsules each day for a total of 1,120 mg alfalfa sprout powder and 460 mcg of folic acid or Group C, 2 capsules twice a day for a total of 2,240 mg of alfalfa sprout powder and 920 mcg of folic acid.

All patients underwent a history and physical exam prior to the start of the study and prior to blood samples being obtained. All patients received instruction in a low fat, low cholesterol diet, similar to the previously recommended Step 2, American Heart Association diet. All patients were instructed in exercise in moderation.

The majority of patients in this study were already following this type of lifestyle. Over 50% of the patients were already receiving statin drugs and many of the other patients were intolerant to statins because of myalgias or true rhabdomyolysis.

Many patients were already receiving folic acid.

Results:

1. All patients tolerated the medication well.

2. One patient in the placebo group stopped the medicine because she felt that the drug irritated her stomach.
3. One patient dropped out of Group C for personal reasons.
4. One patient in Group C who was taking 80 mg of an atorvastatin a day discontinued his atorvastatin during the study and therefore he had a marked increase in LDL level and his results were not included in the averages.

The results of the study were encouraging in that the LDL levels decreased in both treatment groups and more than in the placebo group. HDL also increased in both treatment groups and decreased in the placebo group. A surprising potential benefit of this treatment was the lowering of high sensitivity C-reactive protein levels. This has not been previously reported and the possible mechanism for this is not known, unless it is merely on the basis of lowering LDL levels. A similar lowering was not noted in the placebo group.

The results of the study are impressive since the average baseline LDL levels were only 133 and 151 in Groups B and C. The reason for a greater percentage reduction of LDL and raising HDL in Group B is not clear.

A combination of alfalfa sprout powder and folic acid appears to be a reasonable relatively inexpensive method for lowering one's risk for cardiac events. This should be tested in a larger, double blinded prospective trial to see if this not only lowers known cardiac risk factors but also lowers the number of cardiac events.

Lawrence D. Rink, M.D., F.A.C.C.
Clinical Professor of Medicine
Indiana University School of Medicine
February 12, 2003

EXHIBIT B

United States Patent & Trademark Office
Rule 132 Affidavit

Appl. No. : 10/800,608
Applicant : Stephen Truesdale Carney
Filed : March 15, 2004
TC/A.U. : 1655
Examiner : Patricia A. Leith

Sent May 13th 07
Sent June 7-07

Second Affidavit of Lawrence D. Rink

I, Lawrence D. Rink, M.D., F.A.C.C., hereby duly depose and say as follows:

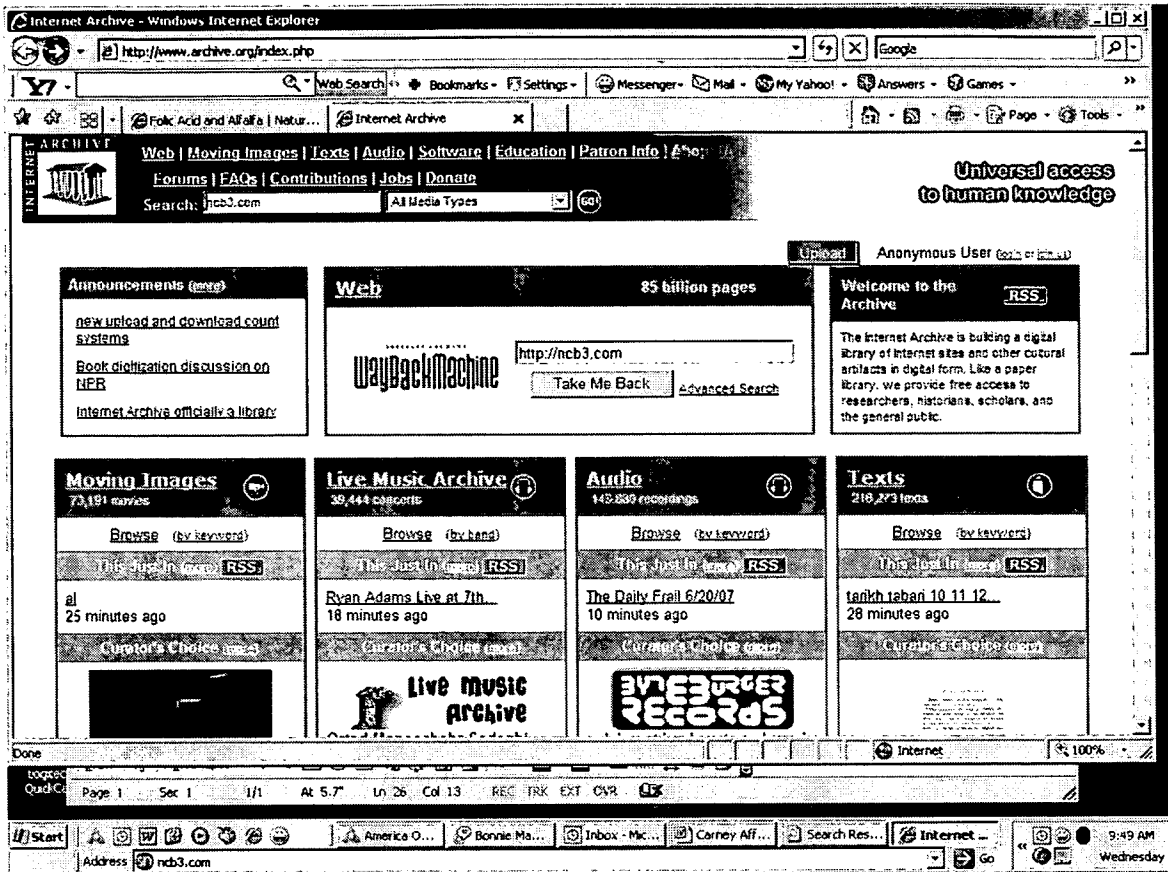
1. I am a Fellow of the American College of Cardiology and have been certified member of the American Board of Internal Medicine, Cardiovascular Disease, since 1983.
2. I have lectured, performed clinical studies and published numerous articles on the issues of cardiovascular disease and hyperlipidemia.
3. Upon the request of Mr. Stephen T. Carney and as a work for hire pursuant to a valid Non Disclosure and Confidentiality Agreement, I conducted the Folic Acid and Alfalfa The FALL Study, (the "Study") described and made part of the above referenced Patent Application.
4. While I am the author of the Study, the Study was completed as a work for hire and on behalf of the Applicant, Stephen T. Carney. As of the date of this Affidavit, I have never caused said Study to be published or decimated to the public.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Signed under the pains and penalties of perjury this 13 day of May, 2007.


Lawrence D Rink, M.D. FACC

Exhibit "C"



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http://web.archive.org/web/20030607220106/http://ncb3.com

Wayback Machine

Enter Web Address: http://

Searched for **http://ncb3.com** 45 Results

Note some duplicates are not shown. [See all](#)
 * denotes when site was updated.

Search Results for Jan 01, 1996 - Jun 20, 2007

1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
0 pages	0 pages	0 pages	0 pages	0 pages	0 pages	0 pages	7 pages	17 pages	14 pages	4 pages	0 pages
						Jun 07, 2003 Jun 12, 2003 Jul 18, 2003 Aug 05, 2003 Oct 18, 2003 Nov 18, 2003 Dec 03, 2003	Feb 12, 2004 Mar 29, 2004 Apr 05, 2004 May 20, 2004 May 26, 2004 Jun 10, 2004 Jun 11, 2004 Jun 15, 2004 Jul 23, 2004 Jul 27, 2004 Jul 28, 2004 Aug 29, 2004 Aug 31, 2004 Sep 18, 2004 Sep 24, 2004 Nov 28, 2004 Dec 17, 2004	Jan 15, 2005 Jan 31, 2005 Feb 03, 2005 Feb 05, 2005 Feb 06, 2005 Feb 08, 2005 Feb 11, 2005 Feb 12, 2005 Mar 11, 2005 Apr 07, 2005 Apr 22, 2005 Apr 24, 2005 Jun 04, 2005 Nov 05, 2005	Jan 14, 2006 Jan 27, 2006 Feb 05, 2006 Feb 18, 2006		

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Natural Cholesterol Balance - Windows Internet Explorer

http://web.archive.org/web/20030607220106/http://ncb3.com/

Natural Cholesterol Balance



Helps maintain healthy levels of:

- HDL, LDL,
- C-reactive protein,
- Homocysteines
- Triglycerides

[Click here for more information](#)

Natural Cholesterol Balance™ is the result of five years of extensive research to control cholesterol naturally. A double blind clinical study of 45 patients was completed in February 2003 and proved the efficacy of the product. Natural Cholesterol Balance™ is all natural and organically grown in a controlled environment.

History
ORDER
Facts
Contact

Lawrence D. Rink
M.D., FACC

Quick Facts

LDL	up to a 16.6% decrease
HDL	up to a 11.2% increase
C-reactive protein	up to a 50.4% decrease
Homocysteine	up to a 11.5% decrease
Triglycerides	up to a 15.0% decrease

Natural Cholesterol Balance - Windows Internet Explorer

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Folk Acid and Alfalfa | Natural Cholesterol Balance

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FOLIC ACID AND ALFALFA
The FALL Study

June 7TH under construction but published on website

History
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Facts
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Background:

There have been reports that alfalfa sprouts will lower total cholesterol and LDL levels in the blood. This has not been tested in a prospective, randomized or blinded trial.

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The trial was six weeks and all patients were instructed to follow a low fat, low cholesterol diet, perform regular exercise in moderation, and to

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Many patients were already receiving folic acid.

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The results of the study are impressive since the average baseline LDL

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- Triglycerides

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in the placebo group.

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Lawrence D Rink

Lawrence D. Rink, M.D., F.A.C.C.
Clinical Professor of Medicine
Indiana University School of Medicine

February 12, 2003

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